REGISTRATION OF DRUG AND BIOLOGICAL PRODUCT

What kind of drug and biological product should be registered?

All kind of drug and biological product should be registered and evaluated for marketing approval:

- New Drug
- Copy Drug
- Biological Product

Who may apply?

Pharmaceutical industries located in Indonesia

How to apply registration for marketing authorization?

There are two steps to be followed:

1. Pre-Registration:
    - Determination of the registration category and evaluation path/timeline
    - Consultation on completeness of registration dossier/document
    - Registration fee
2. Submission of registration dossier:
    - Submit registration dossier according to the registration category completed with bank receipt of registration fee

REQUIREMENT ON REGISTRATION DOCUMENT OF DRUG AND BIOLOGICAL PRODUCT

<u>Registration Document</u>

Part I (Administrative Document and Product Information)
Part II (Quality Document)
Part III (Nonclinical Document)
Part IV (Clinical Document)

<u>Administrative Document</u>

1. Covering letter
2. Application form
3. Applicant declaration
4. Result of pre registration
5. Bank receipt of registration fee
6. Certification and other administrative document:

    Locally manufactured product

    - License of pharmaceutical industry
    - GMP certificate for the dosage form of the product submitted for registration

    Contract manufacturing product

    - License of pharmaceutical industry of applicant

- License of pharmaceutical industry as contract manufacturer
- Contract manufacturing agreement
- GMP certificate of the contact manufacturer for the dosage form of the product submitted for registration

Manufacturing "Under License" Product

- License of pharmaceutical industry
- GMP certificate for the dosage form of the product submitted for registration
- License agreement

Exported product

- License of pharmaceutical industry
- GMP certificate of the manufacturer for the dosage form of the product submitted for registration
- Written approval from destination country that is legalized by an authorized institution in export destination country for drugs that are not permitted for marketing in Indonesia
- Proforma invoice for drugs that are not marketed in Indonesia

Imported product

- License of pharmaceutical industry
- Letter of Authorization
- Certificate of Pharmaceutical Product
- Certificate of Pharmaceutical Product from the country of manufacturer and/or the country where certificate of batch release has been issued
- Site master file of manufacturer (unless previously submitted)
- GMP Certificate from overseas manufacturer (unless submitted in other documents)
- Latest inspection of authorized institution to manufacturer

Technical Data to be Submitted

- Drug with new active ingredient/biological product: Part I, II, III, IV
- Drug with new combination/dosage form/strength: Part I, II, IV
- Drug with new indication/posology: Part I, III, IV
- Copy drug: Part I, II, IV (if required)
- Variations (Data according to the changes):
    1. Modification of composition: Part I, II
    2. Modification of dosage form with the same posology or route of administration: Part I, II
    3. Modification of copy drug strength: Part I, II
    4. Modification of excipients: Part I, II
    5. Modification of specifications and/or analytical methods: Part I, II
    6. Modification of stability: Part I, II

7. Modification of production technology and/or manufacturing site: Part I, II, IV (vaccine)
8. Modification of packaging: Part I, II
9. Modification of package size: Part I
10. Modification of package design: Part I
11. Change of factory name/name of license-holder: Part I
12. Change of copy drug with trade name into copy drug with generic name or inverse: Part I, II (if drug specification is not fulfilled the generic drug requirement)
13. Change of trade name without any change on formula and package form/type: Part I
14. Modification of label claim of copy drug which influence drug safety: Part I
15. Modification of label claim which shall not influence the safety, efficacy and quality: Part I

Where to apply?

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